

- b) a promoter sequence operably linked to the coding sequence, wherein said construct is not packaged in a viral particle, said introducing resulting in introduction of the construct into an intestinal epithelial cell, production of the encoded protein in the intestinal epithelial cell and secretion of the protein from the cell and into the bloodstream of the subject.

19. (New) The method of claim 18, wherein the protein is a fusion protein.

20. (New) The method of claim 18, wherein the protein is altered relative to a wild-type protein.

21. (New) The method of claim 18, wherein the nucleic acid molecule is formulated as a liquid, a solid, a pill, a capsule, a tablet, a solution, a gel, a syrup, a slurry or a suspension.

22. (New) The method of claim 18, wherein the nucleic acid molecule is formulated to facilitate swallowing.

23. (New) The method of claim 18, wherein the nucleic acid molecule is formulated with an agent that protects against degradation.

24. (New) The method of claim 18, wherein the nucleic acid molecule is formulated as a time-release formulation.

25. (New) The method of claim 18, wherein the nucleic acid molecule is associated with an agent that facilitates delivery to the target cell.

26. (New) The method of claim 18, wherein the protein is an immunotherapeutic protein.

27. (New) The method of claim 18, wherein the protein increases an immune response.

28. (New) The method of claim 18, wherein the protein induces immune tolerance.

29. (New) The method of claim 18, wherein the protein is an antigen.

30. (New) The method of claim 29, wherein the antigen is a viral antigen.
31. (New) The method of claim 29, wherein the antigen is a bacterial antigen.
32. (New) The method of claim 29, wherein the antigen is a fungal antigen.
33. (New) The method of claim 29, wherein the antigen is a parasitic antigen.
34. (New) The method of claim 18, wherein the protein is an antibody.
35. (New) The method of claim 34, wherein the antibody is a monoclonal antibody.
36. (New) The method of claim 18, wherein the protein is a clotting factor.
37. (New) The method of claim 18, wherein the protein is a protease.
38. (New) The method of claim 18, wherein the protein is a pituitary hormone.
39. (New) The method of claim 18, wherein the protein is a protease inhibitor.
40. (New) The method of claim 18, wherein the protein is a growth factor.
41. (New) The method of claim 18, wherein the protein is a somatomedin.
42. (New) The method of claim 18, wherein the protein is an immunoglobulin.
43. (New) The method of claim 18, wherein the protein is a gonadotrophin.
44. (New) The method of claim 18, wherein the protein is a chemotactin.
45. (New) The method of claim 18, wherein the protein is a chemokine.

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46. (New) The method of claim 18, wherein the protein is a plasma protein
47. (New) The method of claim 18, wherein the protein is a plasma protease inhibitor.
48. (New) The method of claim 18, wherein the protein is an interleukin.
49. (New) The method of claim 18, wherein the protein is an interferon.
50. (New) The method of claim 18, wherein the protein is a cytokine.
51. (New) A method of delivering a secreted protein into the bloodstream of a mammalian subject, the method comprising:
introducing into the gastrointestinal tract of a mammalian subject by suppository administration a construct comprising:
a) a nucleic acid molecule comprising a coding sequence encoding a protein; and
a promoter sequence operably linked to the coding sequence operably linked to the coding sequence, wherein said construct is not packaged in a viral particle, said introducing resulting in introduction of the construct into an intestinal epithelial cell, production of the encoded protein in the intestinal epithelial cell and secretion of the protein from the cell and into the bloodstream of the subject.

II. REMARKS

Formal Matters

Claims 18-51 are pending after entry of the amendments set forth herein.

Claims 1-17 are canceled without prejudice to renewal.

New claims 18-51 are added. Support for new claims 18-51 is found in the claims as originally filed, and throughout the specification, including at the following exemplary locations: claim 19: page 28, lines 3-8; claim 20: page 29, lines 9-19; claim 21: page 33, lines 6-11; claim 22: page 34, lines 8-10; claim 23: page 12, lines 17-19; page 34, lines 8-10; claim 24: page 34, lines 14-20; claim 25: page 12, lines 15-17; page 35, lines 13-22; claims 26-50: page 16, lines 23-26; page 20, line 22 to page 21, line